CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1669	**Date: May 20, 2016**
	Change Request 9371

SUBJECT: Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

I. SUMMARY OF CHANGES: Section 302 of the Medicare Modernization Act of 2003 (MMA) added a new paragraph to the Social Security Act (the Act) section 1834(a)(20) requiring the Secretary to establish and implement quality standards for suppliers of DMEPOS. All suppliers that furnish such items or services required in the new paragraph as the Secretary determines appropriate must comply with the quality standards in order to receive Medicare Part B payments and to retain a supplier billing number. The covered items and services are defined in the Act. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a new subparagraph for implementing quality standards which state the Secretary shall require suppliers furnishing items and service on or after October 1, 2009 directly or as a subcontractor for another entity, to have submitted evidence of accreditation by an accreditation organization designated by the Secretary.

EFFECTIVE DATE: October 3, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 1669	May 20, 2016	Change Request: 9371

SUBJECT: Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

EFFECTIVE DATE: October 3, 2016
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I. GENERAL INFORMATION

A. Background: Section 302 of the Medicare Modernization Act of 2003 added a new paragraph 1834(a)(20) to the Social Security Act (the Act). This paragraph required the Secretary to establish and implement quality standards for suppliers of DMEPOS. All DMEPOS suppliers that furnish such items or services set out at subparagraph 1834(a)(20)(D) as the Secretary determines appropriate must comply with the quality standards in order to receive Medicare Part B payments and to retain Medicare billing privileges. Pursuant to subparagraph 1834(a)(20)(D) of the Act, the covered items and services are defined in section 1834(a)(13), section 1834(h)(4), and section 1842(s)(2) of the Act. The covered items include:

• DME;

• Medical supplies;

• Home dialysis supplies and equipment;

• Therapeutic shoes;

• Parenteral and enteral nutrient, equipment and supplies;

• Transfusion medicine; and

• Prosthetic devices, prosthetics, and orthotics.

Section 154(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a new subparagraph (F) to section 1834(a)(20) of the Act. In implementing quality standards under this paragraph, the Secretary shall require suppliers furnishing items and services on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted evidence of accreditation by an accreditation organization designated by the Secretary. This subparagraph states that eligible professionals and other persons (defined below) are exempt from meeting the ***September 30, 2009,*** accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such professionals and persons. The eligible professionals who are exempt from meeting the September 30, 2009, accreditation deadline (as defined in section 1848(k)(3)(B)) include the following practitioners:

• Physicians (as defined in section 1861(r) of the Act),

• Physical Therapists,

• Occupational Therapists,

• Qualified Speech-Language Pathologists,

• Physician Assistants,

• Nurse Practitioners,

• Clinical Nurse Specialists,

• Certified Registered Nurse Anesthetists,

• Certified Nurse-Midwives,

• Clinical Social Workers,

• Clinical Psychologists,

• Registered Dietitians, and

• Nutritional professionals.

Additionally, section 154(b) of MIPPA allows the Secretary to specify “other persons” that are exempt from meeting the accreditation deadline unless CMS determines that the quality standards are specifically designed to apply to such other persons. At this time, “such other persons” are specifically defined as the following practitioners:

• Orthotists,

• Prosthetists,

• Opticians, and

• Audiologists.

Therefore, all supplier types (except those listed above) who furnish items and services requiring accreditation, directly or as a subcontractor for another entity, must have submitted evidence of accreditation by an accreditation organization designated by the Secretary on or after October 1, 2009.

B. Policy: VMS shall develop an edit for the HCPCS codes in the product categories designated by MIPPA as requiring accreditation. This edit will auto deny claims paid for these codes unless the DMEPOS supplier has been identified as accredited and verified on their CMS-855S or the DMEPOS supplier is currently exempt from meeting the accreditation requirements. Please refer to CR 7333.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9371.1	PECOS shall add the supplier accreditation codes and including effective and expiration dates for both accreditation and product codes that are found on the									PECOS

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	attachment, to the daily PECOS extract.									
9371.2	VMS shall make system the necessary changes in the VMS system to accept the supplier accreditation codes with the effective and expiration dates transmitted in the PECOS extract.							X		
9371.3	VMS shall make the necessary system changes in the VMS system to house the supplier accreditation codeswith the effective and expiration dates, for the DMEPOS suppliers indicating they will furnish the Products and Services found on CMS 855S, section 3A which require accreditation.							X		
9371.4	The PECOS contractor shall develop and perform a one-time extract to submit the attached supplier accreditation codes including effective and expiration dates with sufficient identifying information to link the accreditation data to the DMEPOS supplier, to VMS by the implementation date.									PECOS
9371.5	VMS shall accept, prior to the implementation date of this CR, the supplier accreditation codes, including effective and expiration dates for supplier accreditation codes via the daily PECOS transmission.							X		PECOS
9371.6	VMS shall make necessary system changes in the VMS system to recognize HCPCS codes in the product categories designated by 1834(a)(13), section 1834(h)(4), and section 1842(s)(2) of the Act.							X		
9371.7	VMS shall accept a transmission from PECOS of all current supplier accreditation codes as well as effective and expiration dates for both non-exempt and exempt DMEPOS suppliers through its daily transmission.							X		
9371.8	VMS shall create an edit which will automatically line item deny claims for HCPCS codes linked to the product codes which require accreditation from non-exempt DMEPOS suppliers where the claim line date of service does not fall between the effective and expiration dates of the supplier's accreditation for that category and it is after the effective date of this CR.				X			X		
9371.9	The DME-MAC shall exempt beneficiary submitted claims from accreditation editing.				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9371.10	DME-MACs shall continue to process claims with dates of service prior to the implementation date of this CR.				X					
9371.11	DME MACs shall pay claims with date of service prior to the implementation date of this CR regardless of the date the supplier is deemed accredited.				X					
9371.12	If a claim was processed and paid prior to the effective date of this CR and the supplier submits an adjustment to that claim after implementation, the adjustment should not be subject to the accreditation edits.				X			X		
9371.13	Contractors shall enable and test the functionality of CR 7333 as part of the implementation of this CR.				X			X		
9371.14	DME MACs shall use Remittance Advice Remark Code N211 – "Alert: You may not appeal this decision" and Claim Adjustment Reason Code CO-B7 – "This provider was not certified/eligible to be paid for this procedure/service on this date of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present," and MSN messages 21.18 and 16.34 for denial of claim.				X					
9371.15	The DME MACs shall automatically deny effected line items submitted on a supplier's claim (as the supplier is liable), if the rendering DMEPOS supplier has not been identified by the NSC as being accredited to supply the specific product/service at the time of date of service (between the effective and expiration dates for both accreditation and product codes) and is not exempt from accreditation.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility		
		A/B MAC	DME	CED

		A	B	H H H	M A C	I
9371.16	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.				X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Sandhya Mathur, 410-786-3476 or Sandhya.Mathur@cms.hhs.gov , Andrew Stouder, 410-786-0222 or Andrew.Stouder@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 1

ATTACHMENT C – HCPCS codes in the product categories designated by Sections 1834(a)(13), 1834(h)(4) and 1834(s)(2) of the Act requiring accreditation with the corresponding Products and Services found on CMS-855S, section 2D, including PECOS-MAC Product Codes.

External Infusion Pumps and Supplies

DM12 – External Infusion Pumps

A4305	DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF 50 ML OR GREATER PER HOUR
A4306	DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF LESS THAN 50 ML PER HOUR
E0779	AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION 8 HOURS OR GREATER
E0780	AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION LESS THAN 8 HOURS
E0781	AMBULATORY INFUSION PUMP, SINGLE OR MULTIPLE CHANNELS, ELECTRIC OR BATTERY OPERATED, WITH ADMINISTRATIVE EQUIPMENT, WORN BY PATIENT

DM24 – External Infusion Supplies

J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS
A4244	ALCOHOL OR PEROXIDE, PER PINT
A4245	ALCOHOL WIPES, PER BOX
A4221	SUPPLIES FOR MAINTENANCE OF DRUG INFUSION CATHETER, PER WEEK (LIST DRUG SEPARATELY)
A4222	INFUSION SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)
A4232	SYRINGE WITH NEEDLE FOR EXTERNAL INSULIN PUMP, STERILE, 3CC
A4602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 1.5 VOLT, EACH
K0552	SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH
K0601	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 1.5 VOLT, EACH
K0602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 3 VOLT, EACH
K0603	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, ALKALINE, 1.5 VOLT, EACH
K0604	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 3.6 VOLT, EACH

K0605	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 4.5 VOLT, EACH

Insulin Pumps and Supplies

DM13 – External Ambulatory Insulin Pump

E0784	EXTERNAL AMBULATORY INFUSION PUMP, INSULIN

DM25 – External Ambulatory Insulin Supplies

Support Surfaces

DM26 - Pressure Reducing Beds/Mattresses/Overlays/Pads – Used

A4640	REPLACEMENT PAD FOR USE WITH MEDICALLY NECESSARY ALTERNATING PRESSURE PAD OWNED BY PATIENT
E0181	POWERED PRESSURE REDUCING MATTRESS OVERLAY/PAD, ALTERNATING, WITH PUMP, INCLUDES HEAVY DUTY
E0182	PUMP FOR ALTERNATING PRESSURE PAD, FOR REPLACEMENT ONLY
E0184	DRY PRESSURE MATTRESS
E0185	GEL OR GEL-LIKE PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH
E0186	AIR PRESSURE MATTRESS
E0187	WATER PRESSURE MATTRESS
E0188	SYNTHETIC SHEEPSKIN PAD
E0189	LAMBSWOOL SHEEPSKIN PAD, ANY SIZE
E0193	POWERED AIR FLOTATION BED (LOW AIR LOSS THERAPY)
E0194	AIR FLUIDIZED BED
E0196	GEL PRESSURE MATTRESS
E0197	AIR PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH
E0198	WATER PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH

E0199	DRY PRESSURE PAD FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH
E0270	HOSPITAL BED, INSTITUTIONAL TYPE INCLUDES: OSCILLATING, CIRCULATING AND STRYKER FRAME, WITH MATTRESS
E0277	POWERED PRESSURE-REDUCING AIR MATTRESS
E0371	NONPOWERED ADVANCED PRESSURE REDUCING OVERLAY FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH
E0372	POWERED AIR OVERLAY FOR MATTRESS, STANDARD MATTRESS LENGTH AND WIDTH
E0373	NONPOWERED ADVANCED PRESSURE REDUCING MATTRESS